



Pfizer Inc.
100 Route 206 North, MS LLA-401
Peapack, NJ 07977
Tel: 908-901-8630

August 5, 2014

Via e-mail and U.S. Postal Service

Mr. Ramón Torres, Chief
Response and Remediation Branch
U.S. Environmental Protection Agency – Region 2
Caribbean Environmental Protection Division
City View Plaza II – Suite 7000
#48 PR-165, Km. 1.2
Guaynabo, PR 00968-8069

**RE: Pfizer Pharmaceuticals, LLC
Carolina Facility Remedial Action Plan
65th Infantry Avenue, Km. 9.7
Carolina, Puerto Rico**

Dear Mr. Torres:

Pfizer Pharmaceuticals, LLC a wholly-owned subsidiary of Pfizer, Inc. (Pfizer), confirms its commitment to voluntarily undertake remedial action at its former manufacturing facility in Carolina (Site) through the implementation of the remedial action plan (RAP), a hard copy of which was provided to Mr. Luis Negrón during our meeting on July 14, 2014.

During the July 14, 2014 meeting with Mr. Luis Negrón, Pfizer summarized their voluntary site investigations and proposed remedial action and to request approval from the Environmental Protection Agency (EPA) for the expedited implementation of the RAP. The Puerto Rico Environmental Quality Board (EQB) was invited; however, no representative attended the meeting.

The original manufacturing plant at the Site was built around 1956-1957 for Parke Davis Company (Parke Davis). Parke Davis owned and operated the facility for pharmaceutical manufacturing from 1956 to 1974. The facility was purchased by Lederle Laboratories, a division of American Cyanamid Company, in 1974 and continued operating as a pharmaceutical facility until 1994. American Home Products took over the facility and operated it until 2002. From 2002 to October 2009, Wyeth Ayerst Lederle, Inc. (Wyeth) operated the facility. Wyeth was acquired by Pfizer on October 2009.

Under Pfizer, the facility manufactured drug products from active ingredients and did not manufacture active pharmaceutical ingredients (API) - i.e. operations did not involve chemical synthesis with solvents.

The Pfizer Site was registered with EPA as a RCRA Large Quantity Generator (LQG) of hazardous wastes (EPA ID No. PRD091197301). The Site consists of 20.33 acres of land located in a mixed-use commercial and industrial area,



and is bounded: on the north by 65th Infantry Avenue followed by various commercial businesses; on the west by an unnamed road followed a vacant lot; on the south by State Road PR-887 followed by warehouses, a supermarket, and a government building; and on the east by various restaurants and a furniture store. The coordinates of the Site are approximately 18 degrees, 22 minutes, 55 seconds north latitude and 65 degrees, 57 minutes, 59 seconds west longitude. The Site once contained eleven (11) buildings structures (Buildings A,B,C,D,E,F,G,H,I, and M) that were used for various purposes, including office space, manufacturing, packaging engineering and maintenance, utilities (chillers, boilers, and emergency generators), laboratory, storage and support areas.

Pfizer discontinued the operations at the Site in late 2012, and except for Buildings A and B all other buildings were demolished during the summer of 2013. Prior to Site demolition, building structure footprints occupied approximately 545,374 square feet (60-65% of the Site). Building foundations that were removed in 2013 have now been graded and seeded. The remainder of the Site is in pre-demolition condition, and is occupied by asphalt or concrete paved surfaces and landscaped areas. The Site is currently for sale for industrial/commercial redevelopment.

In 2010, as part of the Wyeth acquisition due diligence, Pfizer retained Golder Associates Inc. (Golder) to conduct an Environmental Site Assessment (ESA) of the Site. The ESA findings identified the potential for subsurface impacts from past facility operations and/or from off-site upgradient sources. To further characterize and evaluate site conditions, subsurface investigations (Phase 2 Investigation) were conducted in multiple phases from September 2010 through December 2013. Due to access limitations certain investigations could not be conducted until site demolition was completed in 2013.

The Phase 2 Investigation detected chlorinated volatile compounds (VOCs), primarily trichloroethene (TCE) and tetrachloroethene (PCE) and their degradation by products (e.g. 1,1- dichloroethene (DCE), 1,2- DC, cis-1,2-DCE, and vinyl chloride) in soil, soil gas, and groundwater. The highest concentration of VOCs in soil is located in the southern (upgradient) portion of the Site (beneath former building D) by MW-13S (6.2 mg/kg TCE @TB 52 from 22-24" below ground surface, below the EPA RSL of 6.4 MG/KG). No evidence of dense non-aqueous phase liquid (DNAPL) and neither VOCs exceed EPA RSLs in shallow soils (15 feet). VOCs in groundwater are naturally degrading with TCE byproducts (i.e. cis 1,2-DCE & VC), methane, ethane and ethene present. Time-trend monitoring indicates that the plume is relatively narrow and stable.

There is evidence indicative that a contributing source of PCE is from an off-site upgradient source(s), and evidence that the source of TCE is both from off-site and on-site sources. Potable water in the area is supplied by the Puerto Rico Aqueduct and Sewer Authority. Based on a well inventory, there are no groundwater users near or to the north-downgradient of the Site.

A March 2012 risk assessment, compliant with EPA risk assessment guidance documents, determined that VOCs in onsite groundwater and soil gas were below levels of concern for a commercial/industrial site. However, as informed to EPA in our July 14, 2014 meeting, Pfizer developed a RAP to provide a remedial strategy that will mitigate potential exposure pathways for the chlorinated hydrocarbons in soil and groundwater.

The remedial strategy involves treatment of groundwater (in situ) and restricting future uses of the property (i.e. institutional controls). The groundwater remedial alternatives evaluation, focused on remediation/treatment of TCE in shallow source area groundwater. With soil concentrations below EPA RSLs, a significant source within the vadose zone at the Site does not appear to exist (old weathered source); therefore, at this time no soil remediation is deemed



necessary for the Site for protection of groundwater. However, contingent soil remedies were evaluated and may be enacted if a localized significant source is encountered during implementation of the groundwater remediation.

The proposed groundwater remedial action consists of enhanced bioremediation of chlorinated VOCs via amendment injections of sodium lactate and monitoring. Initial injections will be focused on high concentration (source) areas and the downgradient margin (north side) of the Site, and performance monitoring to evaluate effectiveness of design specifications. Sodium Lactate is a safe and effective electron donor amendment. It is a field tested and proven amendment for chlorinated VOC remediation and its use has been approved in many EPA regions, including Region 2. Based on performance monitoring results, site-specific remedial parameters can be refined (e.g. injection, distribution and concentrations).

The areas where the remedial action is initially proposed to be implemented include:

- 1) Area A - Northern Property Boundary (near MW-07S/D)
- 2) Area B – Downgradient Source Area (near MW-02S and TB-46)
- 3) Area C – Source Area (former lyophilizer area of Building D)

If authorized by EPA, the RAP can be implemented (injections/monitoring) during the third (3rd) quarter of 2014.

I am including a copy of the Summary Site Environmental Conditions and Remedial Action Plan presentation that was discussed in our July 14, 2014 meeting – a copy of which was forwarded to Mr. Negron via email and also a copy of the RAP.

We would sincerely appreciate EPA's expedited approval of the RAP so that we can move forward with Site remediation, which will help ensure protection of human health and the environment and facilitate Site redevelopment.

Should you need additional information so not hesitate to contact me at 908-901-8630.

Sincerely,

A handwritten signature in blue ink that reads "William G. Gierke".

William G. Gierke, P.G., Senior Manager
Pfizer Inc.

cc. J. Font, EPA
L. Negrón EPA
L. Vélez, EQB